UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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ABBOTT LABORATORIES ET AL.
Plaintiffs,
-against-

ADELPHIA SUPPLY USA ET AL.
Defendants.
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NOT FOR PUBLICATION
MEMORANDUM & ORDER
15-CV-5826 (CBA) (MDG)

AMON, Chief United States District Judge:

BACKGROUND

In this trade-infringement action under the Lanham Act, Abbott Laboratories, Abbott Diabetes Care Inc., and Abbott Diabetes Care Sales Corp. (collectively, "Abbott") request a preliminary injunction against defendants, who are pharmacies, distributors, and individuals associated with them.[1] The defendants who have appeared do not dispute that they sell "gray market" Abbott products—specifically, FreeStyle diabetes test strips designed for sale internationally—to U.S. consumers.[2] Abbott argues that the likely confusion caused by

[1] The defendants are numerous, and their participation in this lawsuit has varied widely.

The defendants who have appeared and oppose Abbott's request for a preliminary injunction (hereinafter the "opposing defendants," collectively) are, as grouped by their opposition papers: Adelphia Supply USA, Yudah Neuman, Reuven Sobel, and Moses Neuman (collectively, "Adelphia"); Save Rite Medical.com LLC ("Save Rite"), Marc Kaplan, Matrix Distributors, Inc. ("Matrix"), Christopher Benevent, Seth Grument, Dream Cereal Inc., and Douglas Hauck (collectively, the "Save Rite defendants"); H&H Wholesale Services, Inc., Howard Goldman, and Lori Goldman (collectively, "H&H"); and Lev RX Corp. and Kira Levkouskaya (collectively "Lev Rx").

The defendants who have reached stipulated agreements with Abbott for preliminary injunctions (hereinafter the "stipulating defendants") are: Papoutsanis USA, LCC, George Drogaris, D.K.Y. Enterprises, Inc., Kim Ping Jim, Estates Pharmacy, Inc., Mohammed Nuruddin, Eliyahus Pharmacy, Inc., and Ilias Mlabasati. (See D.E. # 94, 103, 122.)

The defendants who have not yet appeared (hereinafter the "non-appearing defendants") are: OSD Capital, Inc., Overstockdrugstore.com LLC, Rick Evenson, Budget Health Corp., John Fandetti, Maria Fandetti, Lori Blue, Anthony Meola, Mark D. Henkin, Berkeley Drug Inc., Majid Hameed, Eugene Ha, Careway Pharmacy Inc., Anatoliy Fain, Harrico-Galler Drug Corporation, John Gallagher, Haber J&N Inc., Naomi Haber, Jerry Haber, Norstrand Pharmacy, LCC, Sarathchandra Adusumalli, Hemagiri Gayam, Global Care Pharmacy, Inc., TGIS Pharmacy, Inc., Sajid Javed, Bay Pharmacy Inc., Irene Piker, B & T Marlboro Pharmacy, Inc., Anatoly Gorokhovsky, Larke Drugs, Inc., Prasad Venigalla, La Ruche Pharmacy, Inc., Sunil B. Patel, and John Does 1–10.

[2] Gray goods are "goods that are manufactured under authorization from the trademark holder, are legally purchased outside the United States from authorized distributors, and are then imported by persons other than the trademark holder and without the markholder's permission." Zino Davidoff SA v. CVS Corp., 571 F.3d 238, 241 (2d Cir. 2009) (quoting Olympus Corp. v. United States, 792 F.2d 315, 317 (2d Cir. 1986)) (internal alterations omitted).

differences in its international and domestic test trips, as well as the interference with its quality-control prerogatives, warrant enjoining the further domestic sale of the international strips.

On October 9, 2015, the Court granted a temporary restraining order ("TRO") enjoining such sales, an order to show cause why a preliminary injunction should not issue, and limited expedited discovery to identify other potential diverters.[3] (See D.E. # 21.) On November 4 and 5, 2015, the Court held an evidentiary hearing on the request for preliminary injunction.

For the reasons that follow, Abbott's request is granted.

FACTUAL FINDINGS[4]

Abbott owns the family of trademarks that appear on FreeStyle and FreeStyle Lite blood glucose test strips. (See D.E. # 4, Decl. of Geoffrey Potter ("Potter Decl.") ¶ 3 & Ex. 2.) Individuals with diabetes use FreeStyle blood glucose strips to monitor their blood-sugar levels. Abbott sells FreeStyle strips in the United States and around the world. (See D.E. # 9, Decl. of Todd Nelson dated Oct. 6, 2015 ("First Nelson Decl.") ¶¶ 4, 19.) FreeStyle strips are manufactured in Ireland, and a specific stock keeping unit ("SKU") and lot number indicate their intended country or region for distribution. (See D.E. # 10, Decl. of Jeffrey Kelley ("Kelley Decl.") ¶¶ 4–5.) Although the international and domestic strips are themselves identical, their packaging and instructional inserts differ in a number of ways.

First, the U.S. package contains a National Drug Code ("NDC") number and the international version does not. (See D.E. # 5, Decl. of Arul Sterlin dated Oct. 5, 2015 ("First Sterlin Decl.") ¶¶ 6–7.) This NDC code is tied to the complicated pricing scheme of FreeStyle strips within the United States. Abbott sets one list price for all U.S. FreeStyle test strips. (Id.)

[3] Pursuant to Local Rule 50.5, the Honorable Dora J. Irizarry, United States District Judge, conducted the TRO hearing and granted the TRO and expedited-discovery request as the miscellaneous judge.

[4] The factual findings are based on the exhibits introduced into evidence and the testimony of Arul Sterlin, Todd Nelson, and Thomas Kneir at the preliminary-injunction hearing, which the Court found credible.

When dispensing strips to an insured customer—and over 95% of purchasers use insurance—a pharmacy scans the NDC code to be reimbursed by the purchaser's insurance company. (Id.) The insurance company then submits a claim to Abbott, who rebates the insurer a previously contracted-for amount. (Id. ¶ 7.) The domestic list price is higher than the international price because of this arrangement. (Id. ¶ 9.) Without an NDC code, however, test strips cannot be scanned, reimbursed, or rebated. (Id. ¶ 11.) In order for a pharmacy to be reimbursed for international test strips that lack an NDC code, the pharmacy would need to scan the NDC code from a box of domestic test strips. (See First Nelson Decl. ¶¶ 11–12.) Abbott's records support a finding that this practice actually took place. (See Tr. of Nov. 4, 2015, Hr'g, Test. of Todd Nelson ("Nelson Test.") at 179:17–180:5.)

Second, the instructional insert for the U.S. strips directs users to obtain blood from any of three "test sites" on their bodies: finger, upper arm, or palm. (First Sterlin Decl. ¶¶ 10–11.) The international version lists seven test sites: finger, upper arm, palm, back of hand, forearm, calf, and thigh. (Id. ¶ 12.) Before 2009, domestic strips listed these seven test sites as well. (See Tr. of Nov. 4, 2015, Hr'g, Test. of Arul Sterlin ("Sterlin Test."), at 102:3–5.) But in 2009, Abbott changed the chemistry of the FreeStyle strips and sought premarket clearance from the Food and Drug Administration ("FDA") for the new strips. (See D.E. # 58, Decl. of Arul Sterlin dated Oct. 16, 2015 ("Second Sterlin Decl.") ¶¶ 9–10 & Exs. 1–4.) It requested approval for all seven possible test sites. (Id.) The FDA determined, however, that blood drawn from the back of the hand, the forearm, the calf, and the thigh produced insufficiently accurate results. (See id.; see also id. Ex. 1 at 4, Ex. 2 at 4, Ex. 3 at 4.) The FDA therefore instructed Abbott not to list those four sites. (Id.)

Third, the packaging and instructional inserts for the U.S. strips are in English and Spanish. (First Sterlin Decl. ¶ 16 & Ex. 9.) The packaging and instructional insert for the international strips include other languages and may not include English at all, depending on their intended distribution country. (Id. ¶ 16 & Exs. 10–14.)

Fourth, the international packaging contains various symbols unaccompanied by explanatory text, which the domestic packaging does not. (Id. ¶¶ 18–19.) The FDA does not approve the use of symbols for consumer labeling. (See id. ¶ 18 & Ex. 15.)

Fifth, the international products list measurements in millimoles per liter and in Celsius, while the domestic products use U.S. customary units of milligrams per deciliter and Fahrenheit. (Id. ¶¶ 20–21 & Ex. 16.) In 2009, the FDA expressly instructed Abbott to provide the correct U.S. units of measurement on its strips distributed in the United States. (See Second Sterlin Decl. ¶ 12 & Ex. 1 at 8.)

Sixth, the international product omits the written warnings "Do not reuse" and "For in vitro diagnostic use." (First Sterlin Decl. ¶ 23.)

Seventh, although FreeStyle strips are approved internationally for use in any meter with FreeStyle technology, domestically they are approved only for specific meters, and the U.S. package indicates as much. (Id. ¶ 24.)

Eighth and finally, the domestic package lists a U.S. toll-free phone number for users to call with questions, while the international package lists a foreign phone number. (Id. ¶ 14.) In 2009, the FDA instructed Abbott that the U.S. customer care phone number should be prominently stated. (See Second Sterlin Decl. ¶ 13 & Ex. 5 at 10.) Calls to the U.S. toll-free number go to Abbott's domestic call center. The call center instructs customers on the use of FreeStyle strips and receives customer feedback, inquiries, and complaints. (See D.E. # 11,

Decl. of Karen P. Gillis ("Gillis Decl.") ¶¶ 3–4.) Abbott logs consumer calls, categorized by the issue addressed. (Id. ¶ 5.) Abbott tracks these calls and analyzes them for larger trends. (Kelley Decl. ¶ 6.) If Abbott identifies an issue warranting a recall, it directly notifies distributors, retailers, pharmacies, and (where possible) consumers and doctors in the country or region that received the affected strips. (Gillis Decl. ¶ 7.)

Operators at the U.S. call center are only trained in the domestic product. (Id. ¶¶ 4–8.) They are not authorized to advise on the international product. (Id.) In response to inquiries about the international strips, the U.S. call center replaces the international product with the U.S. version. (Id. ¶ 9.) Because the international packaging does not list the U.S. toll-free number, however, Abbott generally receives few of these calls. (Id. ¶ 11.) Yet Abbott has received an increased number of calls concerning international strips at the domestic call center since early 2015. (Id. ¶ 12.) While investigating this apparent increase in international test strips within the United States, Abbott identified the defendants in this case. (See D.E. # 105, Decl. of Thomas J. Kneir dated Oct. 29, 2015 ("Second Kneir Decl.") ¶¶ 5–9.)

As part of its ongoing product-security efforts, Abbott makes frequent "buys" from distributors and wholesalers. (See Tr. of Nov. 5, 2015, Hr'g, Test. of Thomas Kneir ("Kneir Test."), at 263:22–23.) For example, as part of its investigation of the resale of not-for-retail-sale test strips, Abbott has made approximately two buys per year from H&H since at least 2006.[5] (See Kneir Dep. at 153:6–16; 229:4–9; 232:6–10.) From 2006 to 2012, those buys returned only the (unauthorized) not-for-retail-sale test strips. (See Kneir Test. at 289:21–23.) But in 2013, a buy included some international test strips. (See id. at 289:24–290:4.) Abbott traced these strips

[5] In 2002, Abbott sent a cease-and-desist letter to H&H concerning a different product. (See Kneir Dep. at 53:2–6.)

to the United Kingdom. (Id. at 290:5–9.) In two additional buys from H&H that year, Abbott received no international strips. (Id. at 290:10–16.)

Evidence of international test-strip diversion increased in 2014. In early 2014, Abbott discovered that test strips intended for distribution in India and Israel were being sold within the United States. (See D.E. # 6, Decl. of Thomas J. Kneir dated Oct. 8, 2015 ("First Kneir Decl.") ¶ 14.) It identified Adelphia as the distributor. (Id.) An Adelphia salesperson stated that Adelphia had 100 cases of international test strips.[6] (Id. ¶ 6.) Abbott traced the product it had discovered to its original Indian and Israeli sources, stopped the sales, and worked with the distributors there to put additional safeguards in place to prevent further sales. (See Second Kneir Decl. ¶¶ 14–16.) Additionally, Abbott informed the FDA Office of Criminal Investigations ("OCI"). (Id. ¶ 17.)

In August 2014, Abbott made two buys from H&H. (Kneir Test. at 290:20–21.) It bought two cases of not-for-retail-sale strips (i.e., 24 cartons) and received no international strips. (Id. at 290:22–23.) Then, while investigating stolen lots of test strips, Abbott ordered two sealed cases from H&H. (Id. at 290:24–291:2.) It received 22 loose cartons instead, two of which were international strips. (Id. at 291:3–4.) It traced those boxes back to the United Kingdom. (Id. at 291:9.)

In September 2014, Abbott attempted to buy international strips from Adelphia again, but could not, which suggested that Adelphia's gray-market distributing had been stopped. (See Second Kneir Decl. ¶ 18.)

The diversion of international strips then became more pronounced, however. (Id. ¶ 19.) In December 2014 and January 2015, Abbott identified Matrix and, again, Adelphia as potential

[6] One case contains 12 cartons; cartons, also called boxes, typically contain 50 strips each. (See First Kneir Decl. ¶ 12.)

diverters. (Id.) On March 18, 2015, FDA OCI requested that Abbott refrain from contacting Matrix, whom FDA OCI was investigating. (Id. ¶ 21 & Ex. 1.) On June 8, 2015, FDA OCI retracted that request. (Id. ¶ 20.) Also on June 8, 2015, Abbott received a report from its private investigative firm. (Id. ¶ 21 & Ex. 2.) The report stated that the to-date sale of international test strips in the United States in 2015 was already twice that of all of 2014. (Id. & Ex. 2) For example, in March 2015, the most active month shown in the report, 45,000 cartons of international test strips were brought into the United States.[7] (Id. Ex. 2.) Abbott also relied on market-consumption data that showed that more FreeStyle tests strips were being sold to U.S. customers than Abbott manufactured for sale in the United States, further suggesting gray marketing. (See First Nelson Decl. ¶ 8.)[8] In August and again in September 2015, Abbott ordered and received 12 cartons of international test strips from H&H.[9] (Kneir Dep. 161:15–20.) In June, September, and October 2015, Abbott purchased international FreeStyle test strips from each defendant pharmacy and distributor as part of its investigation. (See First Kneir Decl. ¶¶ 11–35 & Exs. 2–24 (describing the sale, and providing images of the product purchased, from each pharmacy and distributor defendant.))

[7] The customs logs that the investigative firm reviewed count "pieces," which the report explains are most likely boxes, or cartons. (Id. Ex.2.)

[8] At the preliminary-injunction hearing, H&H objected to a number of statements in Nelson's declarations, including this one, as relying on underlying documents that H&H had not seen and dependent on inadmissible hearsay. The Court may consider hearsay in a preliminary-injunction hearing, however, see Mullins v. City of New York, 626 F.3d 47, 52 (2d Cir. 2010), and regardless, the alleged hearsay—specifically, the information on which Mr. Nelson personally relied when making certain decisions—was not offered for its truth. Further, H&H sought and was granted limited expedited discovery in anticipation of the hearing; rather than seek any underlying documents to Nelson's testimony then, H&H instead sought "discovery of Plaintiffs and third-parties in the form of documents and depositions." (D.E. # 67.) The Court permitted H&H two depositions, but its open-ended, undefined document request was denied. (See D.E. # 75.) The Court therefore overruled these objections to Nelson's declarations at the preliminary-injunction hearing; nevertheless, the Court takes these arguments into consideration when determining the weight to give this evidence.

[9] During the purchase of strips from H&H, the H&H salesperson told Abbott that it was buying international test strips that were differently packaged than U.S. strips. (Id. ¶ 14; see also D.E. # 91, Decl. of Michael Leonhard ("Leonhard Decl.") ¶ 3.)

STANDARD OF REVIEW

A plaintiff seeking a preliminary injunction must show (1) that there is a likelihood of irreparable harm for which remedies at law would be inadequate; (2) that the balance of hardships tips in the plaintiff's favor; (3) that the public interest would not be disserved by issuing preliminary relief; and (4) that there is either a likelihood of success on the merits or sufficiently serious questions going to the merits. See Winter v. NRDC, 555 U.S. 7, 20 (2008); Am. Civil Liberties Union v. Clapper, 785 F.3d 787, 825 (2d Cir. 2015); Salinger v. Colting, 607 F.3d 68, 79–80 (2d Cir. 2010). Preliminary injunctive relief is an extraordinary remedy that requires the plaintiff to carry the burden of persuasion by a clear showing for each factor. Mazurek v. Armstrong, 520 U.S. 968, 972 (1997).

LEGAL CONCLUSIONS

I. Likelihood of Success on the Merits

To issue a preliminary injunction, the Court must determine that Abbott is likely to succeed on the merits of its underlying trademark-infringement claim. Because Abbott seeks a prohibitory injunction, not a mandatory one, it need only show a likelihood of success, rather than a substantial likelihood. See Louis Vuitton Malletier v. Dooney & Bourke, Inc., 454 F.3d 108, 114 (2d Cir. 2006) (finding the district court abused its discretion by requiring substantial likelihood of success on the merits to issue a prohibitory injunction in a trademark-infringement action).

To succeed on its Lanham Act claim, Abbott must show a likelihood of consumer confusion.[10] Consumer confusion over counterfeit goods is typically measured by the nine

[10] Abbott also must show that the FreeStyle marks merit protection. See Gruner + Jahr USA Publ'g v. Meredith Corp., 991 F.2d 1072, 1075 (2d Cir. 1993). Abbott presents its certificates of registration, (see Potter Decl. Ex. 2), which are prima facie evidence that the marks do merit protection, see Lane Capital Mgmt., Inc. v. Lane Capital Mgmt., Inc., 192 F.3d 337, 345 (2d Cir. 1999), and the defendants do not contest this.

Polaroid factors. See Polaroid Corp. v. Polarad Elecs. Corp., 287 F.2d 492 (2d Cir. 1961). But those factors are less helpful in the context of gray-market goods, which use identical marks, are sold in the original packaging, and are obtained legitimately from the manufacturer. See Original Appalachian Artworks, Inc. v. Granada Elecs. Inc., 816 F.2d 68, 74 (2d Cir. 1987) (Cardamone, J., concurring). Generally, the trademark holder does not have a right under the Lanham Act to control unauthorized resales as long as the goods sold are genuine, under the so-called "first-sale doctrine." See Bel Canto Design, Ltd. v. MSS Hifi Inc., 837 F. Supp. 2d 208, 222 (S.D.N.Y. 2011). Two types of goods, however, are not considered genuine and therefore may give rise to Lanham Act liability. First, goods that are not intended for domestic sale and are materially different from domestic goods. See Original Appalachian, 816 F.2d at 73. Second, goods sold in contravention of legitimate, established, substantial, and nonpretextual quality-control measures that the trademark holder follows, the sale of which will diminish the value of the mark. See Warner–Lambert Co. v. Northside Dev. Corp., 86 F.3d 3, 6 (2d Cir. 1996). These tests both serve as proxies for the fundamental question under the Lanham Act: whether consumer confusion is likely. See Nitro Leisure Prods., L.L.C. v. Acushnet Co., 341 F.3d 1356, 1362 (Fed. Cir. 2003).

As an initial matter, H&H argues that consumer confusion is not likely for its customers because, as a wholesaler, it sells to sophisticated pharmacies that know they are buying international test strips. (See D.E. # 89, H&H Defs.' Mem. of Law in Opp. to Pls.' Application for Prelim. Inj. Relief ("H&H Mem.") at 2.) H&H further argues that when selling international strips, it fully discloses that fact, (see id. at 17), and that H&H in fact disclosed this to Abbott's buyer, (see id.). In support, H&H produces an invoice showing the sale of strips labeled "INT," (see D.E. # 92, Decl. of Howard Goldman ("Goldman Decl.") Ex. 2), and the affidavit of the

account executive who sold Abbott international strips, which states that he notified the buyer that he was purchasing international test strips intended for distribution abroad, (see Leonhard Decl. ¶ 3). H&H argues that its disclosure prevents any confusion and Abbott is therefore unlikely to succeed on the merits against H&H. (See id.)

This argument might have some limited appeal were the only difference in the test strips their intended international destination. But as Abbott points out, no evidence suggests that H&H prevented likely confusion over the missing NDC codes and toll-free numbers; foreign measurements, languages, and symbols; or test sites not approved by the FDA. (See D.E. # 104, Reply Mem. of Law in Further Support of Pls.' Request for Prelim. Inj. ("Abbott Reply") at 14.) And no testimony was offered to show that any sufficient disclosure was made to the end-user patients. Further, H&H cites no case law supporting the proposition that a distributor of materially different gray goods is not liable for the downstream confusion of consumers. Indeed, infringers are generally liable for not just point-of-sale confusion, but for post-sale confusion as well. See Mastercrafters Clock & Radio Co. v. Vacheron & Constantin-Le Coultre Watches, Inc., 221 F.2d 464 (2d Cir. 1955) (holding that likely confusion to those besides the purchaser is actionable); see also 4 McCarthy on Trademarks and Unfair Competition §§ 23:7, 100 (4th ed.) ("Where a product is sold both to consumers and to wholesalers and retailers, the issue of likelihood of confusion will usually revolve around the less knowledgeable consumer.").[11]

[11] Abbott also argues that "[i]n any event," H&H would be committing contributory infringement. (See Abbott Reply at 14–15.) H&H responds that Abbott has not shown that it intentionally or knowingly induced others to infringe. (See Tr. of Nov. 5, 2015, Hr'g, Shaeffer Summ., at 394:19–23.) The Court need not decide whether H&H could be liable as a contributory infringer, however, since H&H itself sells the gray goods (unlike the typical contributory-infringement case, where the contributor sells a non-infringing product, which it knows that or intends for its customers to use to infringe on a trademark). Cf. Inwood Labs., Inc. v. Ives Labs., Inc., 456 U.S. 854 (1982).

H&H's limited disclosure to its pharmacy customers therefore does not exonerate it from liability for any otherwise likely confusion.

H&H and the Save Rite defendants next mount a procedural challenge to the claim of material difference: that Abbott cannot sue to enforce the Food, Drug and Cosmetics Act ("FDCA"). H&H argues that Abbott is unlikely to succeed on the merits because the FDCA does not grant a private right of action. (See H&H Mem. at 18–20.) This argument is meritless. Abbott is not suing to enforce FDA regulations. It merely refers to their content to highlight the differences between the international and domestic products that customers would likely consider material. See Novartis Animal Health US, Inc. v. Abbeyvet Export Ltd., 409 F. Supp. 2d 264, 267 n.3 (S.D.N.Y. 2005). The Save Rite defendants make a parallel argument: that the international test strips are not in fact "misbranded" under 21 U.S.C. § 352. (See D.E. # 82, Safe Rite Defs.' Mem. of Law in Opp. to Pls.' Motion for Prelim. Inj. ("Save Rite Mem.") at 12–13.) This point is equally irrelevant. The question at issue in this litigation is not whether the differences between the domestic and international strips constitute "misbranding," but only whether consumers would likely think those differences material.

A. Material Differences

The Court finds that a consumer would likely consider the differences Abbott identifies to be material. These differences are subtle, but "it is by subtle differences that consumers are most easily confused." Societe Des Produits Nestle v. Casa Helvetica, Inc., 982 F.2d 633, 640, 641 (1st Cir. 1992). For that reason, courts apply a "low threshold of materiality" in gray-goods cases, "requiring no more than a slight difference which consumers would likely deem relevant when considering a purchase of the product." Zino Davidoff, 571 F.3d at 246. Here, consumers are likely to find it relevant that their test strips' packaging contains unexplained and unfamiliar

symbols, atypical warnings, international units of measurement, and different languages. See, e.g., Original Appalachian, 816 F.2d at 73 (finding foreign-language packaging and documents material); Johnson & Johnson Consumer Cos., Inc. v. Aini, 540 F. Supp. 2d 374, 387 (E.D.N.Y. 2008) (finding different warnings material); Abbeyvet, 409 F. Supp. 2d at 267 (finding international units of measurement material). Such differences are especially significant since the packaging lacks the toll-free number provided to domestic users. Calling that number might otherwise clear up a user's confusion—although as Abbott points out, the U.S. call-center operators are not trained to assist consumers with the international product anyway. (See Gillis Decl. ¶ 8.) Finally, and most glaringly, consumers would certainly find it relevant that their insert instructs them to test from four sites on their bodies that the FDA specifically rejected as insufficiently reliable. See, e.g., Helen Curtis, Inc. v. Nat'l Wholesale Liquidators, 890 F. Supp. 152, 159 (E.D.N.Y. 1995) (finding deviation from FDA regulations material). These differences satisfy the low threshold of materiality that distinguishes genuine from non-genuine gray goods.

Only H&H actively contests the materiality of these differences. H&H does not dispute these differences as a factual matter, but argues that customers would not find them relevant. (See H&H Mem. at 20–24.) H&H concedes that numerous cases have found deviations from FDA regulations to be material, but argues that because FDA compliant information is available—namely consumers' doctors and testing-device manuals—such deviations are immaterial in this case. (See id. at 21–22.) Indeed H&H attempts to explain away all the differences besides the missing toll-free number and NDC code by arguing that consumers may rely on other sources to inform them about the proper use of their strips. (See id. at 24.) But Abbott rightly responds that the contradictions between the instructions on the international strips and those given by doctors or user's manuals only increases the likelihood of consumer

confusion. (See Abbott Reply at 17.) And these contradictions are not quickly resolved, since the toll-free number for assistance is absent. Finally, although the lack of the NDC number does not affect the cost to insured users, who pay the same co-pay whether they receive a domestic or international box, surely consumers would find it relevant that their insurance company is either fraudulently reimbursed for their medication or not reimbursed at all. In short, none of H&H's arguments persuasively shows that these differences fall below the low threshold of materiality required.[12]

B. Quality Control

The Court finds that no opposing defendant convincingly contradicts Abbott's claim that the differences Abbott identifies interfere with its quality control. The right to control the quality of goods manufactured and sold under the holder's trademark is "[o]ne of the most valuable and important protections afforded by the Lanham Act." El Greco Leather Prods. Co. v. Shoe World, Inc., 806 F.2d 392, 395 (2d Cir. 1986). As part of its quality-control efforts, Abbott monitors its market, fields customer inquiries, and investigates complaints. (See Gillis Decl. ¶¶ 4–5.) The call center collects these data and analyzes them for larger trends. (See id. ¶ 5.) Sometimes, this results in a targeted recall of the product going to an affected country, particularly recalls based off regulatory requirements. (See Kelley Decl. ¶¶ 4–9.) Targeted recalls are more efficient,

[12] At the preliminary-injunction hearing, H&H argued that Polymer Technology Corp. v. Mimran, 37 F.3d 74 (2d Cir. 1994), controls this case. Polymer dealt with retail and professional lines of contact lens solution, both sold domestically. The Polymer court therefore did not apply Original Appalachian Artwork and evaluate goods not intended for U.S. sale for material differences. Instead, Polymer applied the test for unauthorized distribution, asking whether any contractual provision or notice of the manufacturer's intent restricted the distributor and, if so, whether failure to follow the restriction confused the consumer. Id. at 80. The legal questions, then, are quite different from those facing the Court in the instant case. Although there are some factual similarities with respect to consumer confusion, none are especially helpful to H&H. For example, Polymer determined that the retail sale of solution marked "For Professional Distribution Only" would not by itself confuse consumers. Id. at 80. But here, the differences are more numerous and more significant. Additionally, there the retail packaging did not violate FDA regulations—even though it contained slightly different information—because the required information appeared on the package insert. Id. at 78–79. But here both the package and the insert of the international FreeStyle strips deviate from FDA regulations, and neither remedies the other.

more effective, and less disruptive than market-wide recalls, which can lead to over- or underreaction by consumers and pharmacies. (See id.) Abbott's affidavits demonstrate that it has in place and abides by established, legitimate, substantial, and nonpretextual quality-control measures.[13] See Warner-Lambert, 86 F.3d at 6. The defendants offer no refutation. And the defendants' sale of goods outside this quality-control system will diminish the value of Abbott's mark. See id. For example, Abbott will be unable to execute effective targeted recalls, since it will not know in what country the product to be recalled can be found. Instead, it will be forced to recall none or all of a product. See Zino Davidoff, 571 F.3d at 243–45 (finding interference with targeted recalls a sufficient quality-control concern under the Warner–Lambert test).

H&H's arguments to the contrary are not persuasive. First, H&H argues that Abbott cannot show that the product is inferior because Abbott does not allege that H&H altered, tampered with, or sold expired test strips. (See H&H Mem. at 25–26.) But such a showing is not necessary.[14] The actual quality of the goods is irrelevant if the defendant interferes with the trademark holder's quality-control standards. See Zino Davidoff, 571 F.3d at 245–46 (citing El Greco, 806 F.2d at 395). Second, H&H argues that Abbott cannot raise a quality-control argument because it has not taken the step of recalling all of its strips in light of the gray goods in the domestic market and that it has been slow to recall products in the past. (See H&H Mem. at 26; Goldman Decl. ¶ 17.) This argument is similarly irrelevant to whether H&H and the other defendants interfere with Abbott's ability to control its product by effecting a targeted recall in a

[13] Thus distinguishing Polymer, which rejected the plaintiff's quality-control arguments because the company itself did not follow the procedures it claimed that the defendant was undermining. Polymer, 37 F.3d at 78–79.

[14] H&H misreads Zip International Group, the case it cites in support of this proposition. Zip Int'l Grp., LLC v. Trilini Imports, Inc., 09-CV-2437 (JG) (VVP), 2011 WL 2132980 (E.D.N.Y. May 24, 2011). The Court in Zip did not grant summary judgment because a trademark holder could not show the foreign product to be of inferior quality; that holding would contradict clear Second Circuit law. The Zip Court in fact granted summary judgment not under the quality-control test, but under the material-difference test, because the products at issue there were not materially different.

country. See Zino Davidoff, 571 F.3d at 245 ("The fact that none of these instances resulted in a large-scale recall does not help [the defendant]. To the contrary, an important benefit of the [quality-control] system is that it permits [the plaintiff] to keep recalls small and targeted.")

The Court concludes that because the domestic sale of international test strips thwarts Abbott's legitimate quality-control measures, these strips are not considered "genuine" and their sale can give rise to Lanham Act liability. Abbott has therefore made clear showings that it is likely to succeed on the merits under both the materially-different and the quality-control standards.

II. Irreparable Harm

Even if Abbott is likely to succeed on the merits, however, it is only entitled to the drastic remedy of preliminary relief if it is likely to suffer irreparable harm without such relief. A likelihood of irreparable harm is thus the most important prerequisite to preliminary relief. Faiveley Transp. Malmo AB v. Wabtec Corp., 559 F.3d 110, 118 (2d Cir. 2009). A party establishes a likelihood of irreparable harm by showing that there is a continuing harm that cannot be adequately addressed by final relief on the merits and for which money damages are inadequate compensation.[15] N.Y. Pathological & X-Ray Labs., Inc. v. INS, 523 F.2d 79, 81 (2d Cir. 1975). In the trademark context, irreparable harm can arise from injuries to consumer goodwill or a trademark holder's reputation or to the trademark holder's control over that reputation. See, e.g., Nestle, 982 F.2d at 640 ("By its very nature, trademark infringement results in irreparable harm because the attendant loss of profits, goodwill, and reputation cannot be satisfactorily quantified and, thus, the trademark owner cannot adequately be compensated.").

[15] The irreparable-harm requirement necessarily overlaps with the required absence of adequate remedies at law. See Nw. Nat'l Ins. Co. of Milwaukee v. Alberts, 937 F.2d 77, 80 (2d Cir. 1991). A harm adequately compensable by remedies at law is by definition not irreparable—and vice versa.

In the related context of copyright disputes, the Second Circuit recently held that a likelihood of consumer confusion no longer gives rise to a presumption of irreparable harm; rather plaintiffs must show a likelihood that denial of a preliminary injunction would actually cause them irreparable harm. Salinger v. Colting, 607 F.3d at 82 (2d Cir. 2010). Although the Second Circuit has not yet explicitly applied Salinger in the trademark context, see U.S. Polo Ass'n, Inc. v. PRL USA Holdings, Inc., 511 F. App'x 81, 85 (2d Cir. 2013), Salinger itself stated that there was no reason that it "would not apply with equal force to an injunction in any type of case." 607 F.3d at 78 n.7 (emphasis in original). Other courts in this Circuit have therefore applied Salinger in trademark cases. See, e.g., CJ Prods. LLC v. Snuggly Plushez LLC, 809 F. Supp. 2d 127, 140–42 (E.D.N.Y. 2011); Pretty Girl, Inc. v. Pretty Girl Fashions, Inc., 778 F. Supp. 2d 261, 264–66 (E.D.N.Y. 2011). The Court similarly applies Salinger here.

A. Harm to Abbott's Goodwill and Reputation

First, Abbott argues that the likely confusion of its domestic customers over the international test strips will cause damage to its goodwill and reputation that cannot be quantified or recovered. (See Abbott Mem. at 39 (citing U.S. Polo Ass'n v. PRL USA Holdings, Inc., 800 F. Supp. 2d 515, 541 (S.D.N.Y. 2011), aff'd 511 F. App'x 81); Ahava (USA), Inc. v. J.W.G., Ltd., 250 F. Supp. 2d 366, 371 (S.D.N.Y. 2003).) The differences between the two strips, which no defendant refutes, make it likely that Abbott's reputation and goodwill would be irreparably harmed absent preliminary relief. These differences are precisely the type likely to frustrate consumers and cause them to lose goodwill toward Abbott and damage its reputation. For example, a domestic buyer receiving the international strips would likely be frustrated when she brings her strips home and, wondering how to store them and whether she may reuse them, finds only Celsius temperatures and unfamiliar symbols for explanations. If she looks at the

instructional insert for clarification, she may well find no English instructions—and even if she can read the directions, they will instruct her to test from sites rejected by the FDA. When she decides to contact Abbott for help, she will find only an international number, not a U.S. toll-free phone number. Or, worse: the user will attempt to follow the international instructions and store the strips at the wrong temperature, test from the wrong sites, reuse the strips improperly, and only discover after the fact that Abbott's product has misled her. In any scenario, Abbott is likely to lose goodwill and suffer reputational harm when a domestic user receives international test strips.

The opposing defendants' arguments to the contrary are unconvincing. H&H rightly states that Abbott's harm must be actual, real, and imminent, not merely possible, theoretical, or speculative. (See H&H Mem. at 10 (citing Grand River Enter. Six Nations, Ltd. v. Pryor, 481 F.3d 60, 66 (2d Cir. 2007).) H&H's insistence that Abbott's harm is unsubstantiated, however, is incorrect.[16] Abbott indicates that it has recently seen an increase in calls to its U.S. call center related to international goods, (see Gillis Decl. ¶ 3; Abbott Mem. at 40), undermining H&H's suggestion that patients do not rely on any of these material differences, but only their doctors and user's manuals. (See id. at 20–24.) This evidence supports a finding that Abbott's likely harm is not hypothetical, but sufficiently imminent to satisfy the irreparable-harm requirement.

B. Harm to Abbott's Ability to Control Its Reputation

Second, Abbott argues that domestic sales of international test strips interfere with its ability to effectuate its quality-control procedures. Abbott's trademark protects not just its reputation, but its ability to control that reputation through quality-control procedures. El Greco,

[16] H&H also argues that there is no evidence of even one instance of actual confusion. Evidence of actual confusion is not required for Abbott, however; consumer confusion need only be likely. See Bel Canto, 837 F. Supp. 2d at 231.

806 F.2d at 395. "[I]irreparable harm exists in a trademark case when the party seeking injunction . . . will lose control over the reputation of its trademark pending trial." Church of Scientology Int'l v. Elmira Mission of the Church of Scientology, 794 F.2d 38, 43 (2d Cir. 1986) (internal quotation marks omitted). Loss of control over one's reputation is neither calculable nor precisely compensable. Pretty Girl, Inc., 778 F. Supp. at 269 (internal quotation marks and citations omitted).

Abbott polices its reputation through its U.S. call center. (See Gillis Decl. ¶¶ 3–6.) The call center both provides information to Abbott's customers and collects feedback, complaints, and inquiries, including usage information, troubleshooting, literature requests, complaints, and information about product recalls. (Id. at ¶¶ 3–4.) Based on the information from its call center, Abbott decides when and how widely to recall a product. (See id. ¶ 5; Kelley Decl. ¶¶ 4–9.) This reputation control fails when Abbott's domestic customers receive international strips without the U.S. toll-free number or when they call with questions about the international strips that operators trained only on domestic strips cannot answer.

In sum, defendants dispute neither the differences between the two strips nor Abbott's evidence that domestic users have contacted it about the international strips via its U.S. call center. (See Gillis Decl. ¶ 3.) Although Abbott can respond to complaints that are actually phoned in, it cannot identify how many customers experience frustration but do not call, nor can it quantify how much its reputation is damaged in the eyes of the customers who do call. These injuries are not quantifiable and thus cannot be remedied by money damages at law.

In light of the foregoing, the Court concludes that Abbott has therefore satisfactorily shown that, absent preliminary relief, it will suffer irreparable injury to its goodwill and lose control over its reputation.

C. Delay

The opposing defendants contend that Abbott's delay in bringing suit rebuts its claim to irreparable harm. An unreasonable delay in bringing suit can belie an alleged irreparable harm. See Citibank, N.A. v. Citytrust, 756 F.2d 273, 276 (2d Cir. 1985). Preliminary relief has been denied for even short delays—oft-cited dictum from the Southern District of New York suggests two months as a common limit. See Gidatex, S.R.L. v. Campaniello Imports, Ltd., 13 F. Supp. 2d 417, 419 (S.D.N.Y. 1998). It is clear, however, that it is not the length of the delay that is determinative, but its reasonableness. "Courts have not imposed rigid deadlines by which a request for preliminary injunctive relief must be made: In some circumstances, even a relatively brief delay may be too long. . . . If the movant can provide a credible explanation for its inactivity, however, much longer delays may be excused." Id. Plaintiffs can explain delays by showing that they were unaware of their rights or were actively pursuing them in other ways. See Kuklachev v. Gelfman, 629 F. Supp. 2d 236, 250 (E.D.N.Y. 2008) (collecting cases), aff'd, 361 F. App'x 161. The Court will therefore consider delay "generally . . . in assessing irreparable harm," see Tom Doherty Assoc., Inc. v. Saban Entm't, Inc., 60 F.3d 27, 39 (2d Cir. 1995), but only as "one of several factors to consider" in the preliminary-injunction analysis, see Tough Traveler, Ltd. v. Outbound Prods., 60 F.3d 964, 969 (2d Cir. 1995) (Jacobs, J., concurring in the result); accord Marks Org., Inc. v. Joles, 784 F. Supp. 2d 322, 332 (S.D.N.Y. 2011).[17]

[17] Before Salinger, 607 F.3d 68, delay rebutted the presumption of irreparable harm that followed consumer confusion. See, e.g., Kuklachev, 629 F. Supp. 2d at 250. "Since that presumption no longer exists, rebutting the presumption no longer remains an effective remedy for undue delay." Vox Amplification Ltd. v. Meussdorffer, 13-cv-492 (ADS) (GRB), 2014 WL 558866, at *16, report and recommendation adopted by 50 F. Supp. 3d 355 (E.D.N.Y. 2014); see also Marks Org., 784 F. Supp. at 332 ("[Salinger] leaves open the question of what effect Plaintiff's delay should have on the Court's determination of irreparable injury here."). Nevertheless, courts have continued to consider delay after Salinger. See, e.g., Grout Shield Distribs., LLC v. Elio E. Salvo, Inc., 824 F. Supp. 2d 389 (E.D.N.Y. 2011); Marks Org., 784 F. Supp. 2d 322.

For almost all defendants, there is no evidence of delay. None of the pharmacy or pharmacy-owner defendants has attempted to show that Abbott first discovered its infringement before September and October 2015. (See First Kneir Decl. ¶¶ 21–35.) Nor have Save Rite, VIP International, SimpleMed Supply, Budget Drugs Pharmacy, Dream Cereal, or their owners attempted to make any such showing. (See id. ¶¶ 12, 15–18 & Exs. 3–9.) The only questions of delay, then, concern defendants Adelphia, Matrix, and H&H.

H&H attempts to argue that Abbott has delayed bringing suit against it for over 10 years. H&H claims that it has openly marketed and sold international test strips for that long, including at trade shows attended by Abbott. (See H&H Mem. at 11–12.) These facts suggest only that Abbott could have been aware of H&H's activities, not that Abbott was aware. In further support, H&H president Howard Goldman recalls a discussion in approximately 2004 with an employee of TheraSense, from whom Abbott later purchased the FreeStyle test-strip brand, in which the employee expressed knowledge and even support of H&H's gray-goods importing. (See Goldman Decl. ¶ 12.) This decade-old conversation with an unidentified employee of Abbott's predecessor is too attenuated to show that Abbott was aware of H&H's infringement and slept on its rights. Abbott's contradictory evidence—of its efforts at quality control, counterfeit detection, and enforcement—is far stronger. (See generally Second Kneir Decl.) These facts therefore fail to show that Abbott unreasonably delayed.

There have been other delays, however. Abbott first discovered Adelphia's infringement in May 2014, (First Kneir Decl. ¶¶ 3–9), and received small amounts of international strips from H&H in 2013 and August 2014, (Kneir Dep. 156:7–18; 246:17–24; Kneir Test. at 289:24–290:4). Abbott noticed other infringement in late 2014 and early 2015 and an increase in sales of international strips in early 2015. (See First Kneir Decl. ¶¶ 3–9.)

Although Abbott might be expected to immediately sure to enforce its rights upon discovering a counterfeit product, the reasonableness of delay in the context of a gray-goods case is different. Gray-goods distribution often comes from business partners, not business competitors. Much of it occurs on a small or even individual scale. (See Kneir Test. 333:12–18.) And absent material differences or quality-control interference, reselling even international genuine goods is not infringement at all.

In light of these considerations, the Court finds it reasonable that Abbott would seek to curtail gray marketing as a whole by pursuing less expensive and intrusive—but potentially effective—options before turning to litigation. Because Abbott has business relationships with the distributors committing gray-goods infringement, Abbott first addresses it contractually. (See Second Kneir Decl. ¶ 5.) It identifies the source of diverted goods, audits them, and puts protective measures in place. (See Kneir Dep. at 181:8–10; 214:16–22.) This strategy has been successful in the past. (See Second Kneir Decl. ¶¶ 14–16.) Abbott also notifies and cooperates with law enforcement. (See Kneir Dep. at 181:11–13.) But if these strategies fail, it then enforces its rights judicially as it has done here. (See id. at 238:22–25.) Abbott admittedly does not pursue every single instance of small-scale gray marketing; Abbott believed that to do so would exceed even its $1.4 million dollar budget for product protection. (See id. at 168:19–21; 169:4–7; 173:16–25; 174:3–9.) But at no point did Abbot unreasonably sleep on its rights.

Specifically, when Abbott received a small number of international strips from H&H in 2013, it traced the strips to the United Kingdom and then did two additional buys, which returned no international strips. (Kneir Test. at 290:10–16.) Similarly, when Abbott became aware of small-scale infringements flowing through Adelphia during 2014, it traced the goods to India and Israel, and then worked to eliminate the source of the problem rather than Adelphia's discrete

inventory alone (which it nevertheless reported to FDA OCI). (See Second Kneir Decl. ¶¶ 6, 13–16; Kneir Test. at 355:1–3.) It had reason to consider the matter resolved at the end of 2014. (See Second Kneir Decl. ¶ 18.) When Abbott received two cartons of international strips out of 22 from H&H in August 2014, it was reasonable to investigate further rather than immediately seeking an injunction. When Abbott discovered further small-scale infringement in early 2015, this time from Adelphia and Matrix, it pursued the same remedies that had been previously successful and again coordinated with FDA OCI. (See id. ¶ 19.) FDA OCI explicitly asked Abbott to delay pursuing any actions with respect to Matrix until June 8, 2015. (See id.; see also id. Ex. 1.) In contrast, when Abbott discovered in June 2015 that the scale of infringement was far greater than previously thought, Abbott instigated large-scale buys as part of the investigation that identified the defendants in this lawsuit. (See id. ¶¶ 22–24.)

This timeline makes clear that at no time was Abbott sleeping on its rights and delaying suit without reason. Instead, it actively pursued good-faith, non-judicial actions to cease the infringement up until the point where it became clear that its trademark could not be protected without judicial intervention. Defendants' insistence that Abbott should have sent cease-and-desist letters does not undercut the actions it did take—particularly given at least H&H's admission that the cease-and-desist letter it once received from Abbott did not cause it to stop selling that product. (See Tr. of Dep. of Howard Goldman at 52:11–12 ("I have no reason to believe that we would have stopped selling because of this letter.").) Nothing suggests that Abbott's timing was strategic, see Tom Doherty, 60 F.3d at 39, except insofar as it was part of a broader strategy to combat gray marketing. Because the delay is thoroughly explained, it does not negate Abbott's showing of irreparable harm with respect to these defendants.

Abbott has therefore shown that it is likely to suffer irreparable harm to its reputation and consumer goodwill that cannot be remedied with monetary damages but only by preliminary relief and that it was actively enforcing its rights during the time between its discovery of the gray marketing at issue and filing the instant suit.

III. Balance of Hardships and Public Interest

To grant an injunction, the Court must also find that the hardships balance in Abbott's favor and that an injunction would not disserve the public. See Salinger, 607 F.3d at 80 (citing Winter, 555 U.S. at 20; eBay Inc. v. MercExchange, L.L.C., 547 U.S. 388, 391 (2006)). In Abbott's favor, it has and will continue to suffer irreparable harm to its customer goodwill while the international strips are sold domestically. Its efforts and processes nurture and protect that goodwill. The defendants, on the other hand, would be enjoined only from what is already prohibited: selling gray goods that are materially different from their domestic counterparts and interfere with the manufacturer's quality-control procedures. See, e.g., Gayle Martz, Inc. v. Sherpa Pet Group, LLC, 651 F. Supp. 2d 72, 85 (S.D.N.Y. 2009). At the hearing, the opposing defendants argued vigorously that Abbott should have sent all the defendants cease-and-desist letters. (See, e.g. Tr. of Nov. 5, 2015, Hr'g at 421:22–23; 428:7–8). Indeed, Adelphia represented that if Abbott had just asked it to stop selling international strips, it would have. (See Tr. of Nov. 4, 2015, Hr'g at 88:17–20). Abbott is asking them to stop now; defendants have no serious argument that they would suffer the greater hardship if enjoined from conduct that they would have ceased voluntarily. Lastly, Abbott requests an injunction only on the domestic sale of international test strips; nothing in the requested order prevents the defendants from selling the international product back to the market for which it was intended. The balance of hardships therefore clearly favors granting the injunction.

And the public interest would not be disserved by granting such preliminary relief. "In exercising their sound discretion, courts of equity should pay particular regard [to] the public consequences in employing the extraordinary remedy of injunction." Winter, 555 U.S. at 24 (quoting Weinberger v. Romero-Barcelo, 456 U.S. 305, 312 (1982)). The defendants urge that their practice reduces the price of test strips. Yet patients with insurance—95% of buyers—see no benefit. They pay the same amount, but their insurer and Abbott pay unwarranted reimbursements and rebates.[18] The uninsured five percent of buyers might pay less for their strips—but these purchasers do not receive a product intended to be used by the American consumer. Instead, they receive a materially different product likely to cause confusion. Enjoining the sale of a product likely to confuse users serves the public. See, e.g., New York City Triathlon, LLC v. NYC Triathlon Club, Inc., 704 F. Supp. 3d 305, 344–45 (S.D.N.Y. 2010); see also Osmose, Inc. v. Viance, LLC, 612 F.3d 1298, 1321 (11th Cir. 2010) ("[T]he public interest is served by preventing customer confusion and deception."); U.S. Polo Ass'n, 800 F. Supp. 2d 541 ("The consuming public has a protectable interest in being free from confusion, deception and mistake."). An injunction would therefore serve, not disserve, the public interest.

Accordingly, Abbott has satisfied all the requirements for a preliminary injunction.

IV. Defendant-Specific Arguments

The Court briefly addresses arguments particular to certain defendants here.

A. Lori Goldman's Involvement

H&H argues that defendant Lori Goldman, the wife of H&H president Howard Goldman, should not be enjoined. (See H&H Mem. at 7–8.) In response to Abbott's allegation that Mrs. Goldman is H&H's marketing manager, (see D.E. # 1, Compl. ¶ 32), H&H proffers affidavits

[18] In fact, in the long run, it is quite possible that such fraud could cause the cost of the strips to increase.

from both Howard and Lori Goldman that she is a full-time parent who has no involvement in H&H's business activities. (See Goldman Decl. ¶ 19; D.E. # 51, Decl. of Lori Goldman ¶¶ 2–3.) Neither Abbott's evidence nor its reply memorandum attempts to contradict these affidavits, (see Kneir Dep. 20:20–25, 21:1–14; Abbott Reply), and at the preliminary-injunction hearing, Abbott consented to Lori Goldman's exclusion from any preliminary injunction, (see Tr. of Nov. 5, 2015, Hr'g at 446:25–447:5). The Court therefore excludes her from Abbott's preliminary relief.

B. Lev Rx's Voluntary Cessation

Defendant Lev Rx states that it will voluntarily stop selling international test strips until this action is completed or the Court denies a preliminary injunction, and therefore it should not be subject to any injunction the Court issues. (See D.E. # 93.) Voluntary cessation is an important factor bearing on the question of whether a court should grant a preliminary injunction or consider the request moot. Holland v. Goord, 758 F.3d 215, 223 (2d Cir. 2014); see also Register.com, Inc. v. Verio, Inc., 356 F.3d 393, 405 (2d Cir. 2004) (finding that defendants' voluntary cessation before the suit was initiated could lead the district court to decline to issue an injunction, but that it did not prevent the court from granting injunctive relief). The question is whether the record evinces "some cognizable danger of recurrent violation." Robert Stigwood Grp. Ltd. v. Hurwitz, 462 F.2d 910, 913 (2d Cir. 1972). Unlike defendants who take affirmative actions to prevent recurrence, however, Lev Rx here simply avers that it will stop the infringing activity. Cf. Lamar Advertising of Penn, LCC v. Town of Orchard Park, N.Y., 356 F.3d 365, 377 (2d Cir. 2004) (finding mootness where town repealed injurious ordinances). Lev Rx's affidavit alone does not eliminate all cognizable dangers of a recurrent violation. The Court therefore declines to exclude Lev Rx based on its voluntary cessation.

C. H&H's Request for a Disclaimer Instead of an Injunction

Finally, H&H argues that Abbott's irreparable harm could be cured by a disclaimer, making a prohibitory injunction unnecessary. "Where, as here, an infringer attempts to avoid a substantial likelihood of consumer confusion by adding a disclaimer, it must establish the disclaimer's effectiveness." Weight Watchers Int'l, Inc. v. Luigino's, Inc., 423 F.3d 137, 143–44 (2d Cir. 2005). There is a "heavy burden" on H&H to "come forward with evidence sufficient to demonstrate that any proposed materials would significantly reduce the likelihood of consumer confusion." Home Box Office, Inc. v. Showtime/Movie Channel, Inc., 832 F.2d 1311, 1316 (2d Cir. 1987). Far from recognizing this high bar and evincing supporting evidence, H&H instead erroneously suggests that it would be an abuse of discretion for the Court to refuse a disclaimer where one could arguably be remedial. (See H&H Mem. at 15.) This argument misrepresents its case in support, Bell & Howell: Mamiya Co. v. Masel Supply Co., 719 F.2d 42 (2d Cir. 1983), in which the Second Circuit reversed the lower court because the court failed to consider irreparable harm at all before issuing an injunction, not because it declined to issue a disclaimer. Besides citation to inapposite precedent, H&H makes no showing that a disclaimer would significantly reduce consumer confusion. And such a disclaimer would likely be insufficient: affixing a notice to the international package would not resolve the material differences on the instructional insert, and the modification alone might further confuse consumers and cause them to lose goodwill toward Abbott. See Zino Davidoff, 571 F.3d at 246 ("[C]onsumers may regard a product whose packaging has been tampered as inferior and perhaps suspicious. Mutilation of packaging to conceal markings may lead the consumer to suspect that the item is stolen merchandise, or is defective and has been diverted from a recall, or is otherwise untrustworthy."). The Court therefore declines to require a disclaimer in lieu of a prohibitory injunction.

CONCLUSION

For these reasons, Abbott's request for a preliminary injunction is GRANTED. The attached ORDER details the terms of the injunction.

SO ORDERED.

Dated: November 6, 2015
Brooklyn, New York

/s/ Carol Bagley Amon
Carol Bagley Amon
Chief United States District Judge